Laboratory Public Meeting: Payment New Clinical Laboratory Tests for 2006

Date: Monday, July 18, 2005 10:00am - 4:00pm e.d.t.

On-site check-in will begin at 9:30am

Place: Centers for Medicare & Medicaid Services (CMS) Auditorium

7500 Security Boulevard, Baltimore, MD 21244

The meeting is open to the general public to make recommendations on the assignment of payment levels for new codes to be included in the 2006 Medicare Clinical Laboratory Fee Schedule. The meeting announcement is published in the **Federal Register** on Friday May 27, 2005, pages 30734 - 30735. As discussed in more detail in the Federal Register notice, the meeting is intended to provide expert input on the nature of the new test codes and receive recommendations to either crosswalk or gap fill for payment.

Registration will begin June 20, 2005. To register for the meeting, individuals should complete the Internet registration form by July 14, 2005. A confirmation will be sent upon receipt of the registration by CMS. Individuals who wish to make a presentation to recommend assignment of payment for one or more of the new test codes should complete this information on the registration form, prepare a brief presentation (not to exceed 15 minutes), and provide three written copies at the time of presentation. Presenters may also make copies available for up to 50 meeting participants. This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. Photo identification and registration confirmation will be required to enter the building. Vehicles are inspected, at entrance to the grounds, and persons must pass through a metal detector when entering the building. Directions and other information for visitors to the building are available at www.cms.hhs.gov/about/agency/visiting

Also, individuals may listen to the public meeting by dialing 877-203-0044, conference ID number 6097930. Registration is not required for audio listening. Registration, in-person attendance, and 3 written copies of the presentation are necessary to make a presentation on the assignment of payment levels at this meeting. After the on-site presentations, a question and answer period will be opened to both the participants in the room and the audio listeners. The moderator of the meeting will monitor the question and answer period.

The following is a list of the newly created codes that require recommendations on the assignment of payment levels in order to be included in the clinical laboratory fee schedule. The coding changes have been developed by the American Medical Association's Current Procedural Terminology (CPT) Editorial Panel and will not be further discussed at the CMS public meeting. Numbering of the codes has not yet been finalized. However, the identifying information should be sufficient for those knowledgeable in coding for clinical laboratory services.

Chemistry

Code 82270 (revised) Blood, occult, by peroxidase activity (eg, guaiac), qualitative, feces; consecutive collected specimens with single determination, for colorectal neoplasm screening (ie, patient was provided three cards or single triple card for consecutive collection)

1) Code 8227x: single specimen, (eg, from digital rectal exam)

Code 83026 Hemoglobin; by copper sulfate method, non-autmoated

Code 83036 (revised) glycosylated (A1C)

- 2) Code 8303x glycosylated (A1C) by device cleared by FDA for home use
- 3) Code 8363x Lactoferrin, fecal; quantitative
- 4) Code 8369x Lipoprotein (a)
- 5) Code 8370x Liproprotein, blood; electrophorectic separation and quantitation
- 6) Code 8370x high resolution fractionation and quantitation of lipoproteins including subclasses when performed (eg, electrophoresis, ultracentrifugation)
- 7) Code 8370x quantification of lipoprotein particle numbers and lipoprotein particle subclasses (eq. by nuclear magnetic resonance spectroscopy)

Codes 83715 - 83716 (deleted)

Code 83890 Molecular diagnostics; molecular isolation or extraction

Code 83898 (revised) amplification of patient nucleic acid, each nucleic acid sequence

- 8) Code 8390x amplification of patient nucleic acid, multiplex, first two nucleic acid sequences each
 - Code 83901 (revised) amplification of patient nucleic acid, multiplex, each additional nucleic acid sequence (List separately in addition to code for primary procedure)
- 9) Code 8390x lysis of cells prior to nucleic acid extraction (eg, stool specimens, paraffin embedded tissue)
- 10) Code 8390x signal amplification of patient nucleic acid, each nucleic acid sequence
- 11) Code 8390x separation and identification by high resolution technique (eg, capillary electrophoresis
- 12) Code 8391x Mutation identification by enzymatic ligation or primer extension, single segment, each segment (eg, oligonucleotide ligation assay (OLA), single base chain extension (SBCE), or allele-specific primer extension (ASPE))

Immunology

Code 86064 (deleted)

- 13) Code 8620x Cyclic citrullinated peptide (CCP), antibody
- 14) Code 8635x B cells, total count
- 15) Code 8635x Natural killer (NK) cells, total count
- 16) Code 8636x Stem cells, (ie, CD34), total count

Code 86379 (deleted)

17) Code 8648x Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response

Category III code 0010T (deleted)

Code 86585 (deleted)

Code 86587 (deleted)

Microbiology

Code 87205 Smear, primary source with interpretation; Gram or Giemsa stain for bacteria, fungi, or cell types

- 18) Code 8720x complex special stain (eg, trichome, iron hemotoxylin) for ova and parasites
- 19) Code 8790x Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics

Category III code 0023T (deleted)

The 2006 clinical laboratory fee schedule will be effective for services delivered January 1 to December 31, 2006. CMS will issue instructions and fees to Medicare carriers/intermediaries for implementation of the 2006 clinical laboratory fee schedule or after the last week of October 2005. Internet access to the transmittal instructions should be available at www.cms.hhs.gov/manuals/120_OTN and the data file should be available on or after the third week of November 2005 at www.cms.hhs.gov/suppliers/clinlab/ For questions, contact Anita Greenberg by phone 410-786-4601 or anita.greenberg@cms.hhs.gov